

### REMARKS

Applicant notes with appreciation the well reasoned office action embodied in Paper No. 20090304 and the opportunity to distinguish the pending claims over the prior art of record. This amendment is fully responsive thereto.

Claims 1-19, 21, 22, 24-27, and 30-34 are pending in the above identified application.

With entry of this amendment claims 4 and 18 are canceled.

Claims 1 and 15 are currently amended to recite that the plurality of aliquots is applied to a plurality of simultaneous different separation steps. This amendment finds support in the specification as filed *inter alia* paragraphs [0037]-[0038]. Claims 1 and 15 are further amended to recite that the first separation step yields a plurality of uniquely different partially resolved eluates. These amendments find support in the specification as filed *inter alia* paragraph [0039]. Finally, the language of claim 4 as originally filed is recited in claim 1 and the language of claim 18 as originally filed is recited in claim 15. As such, no new matter is added by way of amendment.

Currently, claims 1-12, 14-19, 21, 22, 24-25, 27, 30-32, and 34 are rejected under 35 U.S.C. § 103(a) as unpatentable over Wagner et al. in view of Gygi et al. (PNAS 2000 97(17):9390-9395) and Kachman et al. (Anal. Chem. 2002 74:1779-1791).

Claims 1-6, 8-11, 13, 26, and 33 are rejected under 35 U.S.C. § 103(a) as unpatentable over Wagner et al. in view of Miliotis et al. (J. Chromotography A 2000;886:99-110).

#### **Remarks directed to the rejection of claims 1-12, 14-19, 21, 22, 24-25, 27, 30-32, and 34 under 35 U.S.C. §112, second paragraph as being indefinite.**

In view of the amendments to claims 1 and 15, Applicant submits that claims 1-12, 14-19, 21, 22, 24-25, 27, 30-32, and 34 particularly point out and distinctly claim the subject matter Applicant regards as the invention. Reconsideration and withdrawal of the rejection is solicited.

**Remarks directed to the rejection of claims 1 and 15 under 35 U.S.C. §112, second paragraph as being indefinite.**

In view of the amendments to claims 1 and 15 to incorporate the analyzing step of claims 4 and 18 respectively, Applicant submits that claims 1 and 15 particularly point out and distinctly claim the subject matter Applicant regards as the invention. Reconsideration and withdrawal of the rejection is solicited.

**Remarks directed to the rejection of claims 1-12, 14-19, 21, 22, 24-25, 27, 30-32, and 34 under 35 U.S.C. § 103(a) as unpatentable over Wagner et al. in view of Gygi et al. and Kachman et al., and the rejection of claims 1-6, 8-11, 13, 26, and 33 as unpatentable over Wagner et al. in view of Miliotis et al.**

Applicant incorporates by reference all remarks of record that Wagner fails to teach or suggest all elements of claims 1, 15, or the claims that depend therefrom. Applicant further incorporates by reference all remarks made of record with respect to 35 U.S.C. §103 rejections involving Wagner et al.

Claims 1 and 15 are currently amended to recite that the plurality of aliquots are subjected to a plurality of simultaneous different separation steps. The prior art of record fails to teach or suggest more than one first separation step. Further, Wagner et al. fails to teach or suggest that either the RAM column or the IEX column are used in a simultaneous manner. Indeed, the Wagner et al. method is not possible to accomplish if the RAM column and the IEX column are run simultaneously. Wagner et al. teach: "Elution was performed in a backflush mode in-line with the analytical column." (page 811, right column, first full paragraph.) Further, "the column [IEX] was always operated in-line with the corresponding ion exchange restricted access column [RAM]." (page 811, right column, second full paragraph.) A person of ordinary skill in the art recognizes, in addition, that the usefulness of the IEX column in Wagner et al. depends on a prior separation step by the RAM column such that the two separations could not be run in parallel. As such, Wagner et al. provide no teaching, suggestion, or motivation to

subject a plurality of aliquots to a plurality of simultaneous different separation steps as required by claims 1 and 15 as currently amended.

Claims 1 and 15 are also amended to recite that the first separation step yields a plurality of uniquely different partially resolved eluates. The steps of Wagner et al. that may qualify as a first separation step are: 1) ultrafiltration or 2) RAM column separation. The ultrafiltration step recited in Wagner et al. at page 810, right column, produces a single "eluate." Wagner et al. teach that the ultrafiltration produces a single filtrate. The RAM column of Wagner et al. also produces a single eluate. The RAM column is eluted step-wise. (page 811, "Chromatographic Conditions.") A person having ordinary skill in the art recognizes that a step-elution results in a single, total elution of the column producing a single eluate. Importantly, the apparatus of Wagner et al. will not function if the RAM column is eluted in aliquots as the system depends on a direct feed from the elution of the RAM column to the loading of the IEX column negating the possibility of multiple eluates.

Overall, claims 1 and 15 as currently amended recite steps that are neither taught nor suggested by any cited portion of Wagner et al.

With respect to the teachings of Gygi et al., Kachman et al., and Milotis et al., Applicant incorporates by reference the remarks made of record 29 December 2008. Paper No. 20090304 fails to address these remarks. Specifically, Paper No. 20090304 fails to address failure of Gygi et al. to suggest developing novel techniques that permit large-scale (automation) quantitative comparison of protein expression presented on page 6 and the lack of a reasonable expectation of success and teaching away presented on pages 13 and 14 of the 29 December 2008 submission. The cited portions of Gygi must be read in light of the entire reference. No remarks with respect to the failure of Kachman et al. to teach or suggest affixing a machine readable label presented on pages 7 and 8 are presented in the current office action. Applicant submits that claims 7, 14, 21, 28, 32, and 33, the claims for which Gygi et al. and Kachman et al. are cited, are directed to patentable subject matter. As the teaching of Milotis is directed merely to claims 3, 13, and 26, Applicant submits that these claims are similarly directed to patentable subject matter as Milotis et al. fails to provide the requisite teaching to support the deficiencies in Wagner et al. as identified on pages 15 and 16 of the 29 December 2008 submission.

A *prima facie* case of obviousness is not satisfied by the combination of Wagner et al. alone or in combination with Gygi et al. and Kachman et al. or in combination with Miliotis et al. in that all elements are neither taught nor suggested by the cited prior art. Accordingly, Applicant respectfully requests that the rejections of all the claims under consideration be withdrawn.

**Summary**

Claims 1-19, 21, 22, 24-27, and 30-34 remain pending in the application. Claims 1 and 15 are currently amended. Claims 4 and 18 are canceled. Each of the pending claims is submitted to be in patentable form and directed to allowable subject matter. Reconsideration and withdrawal of the rejections and the passing of this application to allowance are requested. Should the Examiner have any suggestion as to how to improve the form of any of the pending claims, it is respectfully requested that the undersigned attorney be contacted at the telephone number provided below to resolve any outstanding issues.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

Dated: June 24, 2009

Respectfully submitted,

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Docket No.: NEN-22505/16  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Mary Lopez

Application No.: 10/568,215

Confirmation No.: 8128

Filed: March 28, 2006

Art Unit: 1657

For: Parallel process for protein or virus separation  
from a sample

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Examiner: Bin Shen

**STATEMENT OF THE SUBSTANCE OF INTERVIEW**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

A telephonic interview occurred on 09 June 2009 between Examiner Shen, Examiner Weber, and Applicant's representative, Weston Gould. No exhibits were shown in the course of the interview. The interview consisted of a discussion of the pending claims relative to the prior art references of record. Proposed amendments to claims 1 and 15 to recite the presence of distinctly different parallel first separations were agreed to as neither taught nor suggested by Wagner et al.

Entry of this Statement of the Substance of Interview is requested as the Statement is in compliance with 37 CFR 1.133.

Dated: June 17, 2009

Respectfully submitted,

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